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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,775

02/21/2002

Chandra S. Ramanathan

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06/10/2005

EXAMINER

SEHARASEYON, JEGATHEESAN

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PATENT DEPARTMENT
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ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,775

Applicant(s)

RAMANATHAN ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is in response to the amendment and response filed on 2/15/2005. Claims 1-21 have been cancelled. Claims 22 and 29 have amended. Thus, claims 22-37 are pending.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
3. The Office acknowledges the change in title.
4. The Office also acknowledges the changes to the specification and the submission of the substitute specification. Therefore the objection to the specification is withdrawn.
5. The Office acknowledges the receipt of the drawings on 2/21/2002.
6. The Office acknowledges applicants compliance of deposit requirements.
7. The Office acknowledges the receipt of the declaration filed under 37 CFR 1.132.

Claim Rejections - 35 USC § 101

8. Claims 22-37 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record as stated in the Office Action dated 10/5/2004.

Applicants assert that the claimed invention is supported by a specific and substantial utility or a well established utility, and point out that HGPRBMY25 is a functional G-protein coupled receptor (GPCR). Specifically, it is asserted based on the strong homology to other members of the GPCR family members the presence of 7 transmembrane domains within the encoded HGPRBMY25 polypeptide sequence and the presence of a G-protein coupled receptor consensus sequence within the encoded

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HGPRBMY25 polypeptide sequence. Applicants also assert that one skilled in the art would credibly believe that the HGPRBMY25 represents a G-protein coupled receptor based upon the strong homology to other known G-protein coupled receptors; the presence of the 7-transmembrane domains; in addition to the presence of the GPCR consensus sequence which is present in known functional G-protein coupled receptors. Applicants also claim that the instant specification teaches that the human HGPRBMY25 is a functional human G-protein coupled receptor capable of coupling via the promiscuous G-protein G-alpha 15 in addition to teaching that the polypeptide localizes to the cell membrane, which is confirmed by the declaration filed under 37 CFR 1.132 by Feder. Applicants also assert that the demonstration that HGPRBMY25 is capable of functionally coupling to Gq/11 G-proteins is significant since it associates this receptor with the direct regulation of the well-established phospholipase C (PLC) signaling pathway.

These arguments are not persuasive for the following reasons. (1) Amino acid sequence identity to other GPCR proteins is not sufficient for establishing utility because structural analogy to a known compound with a known activity and utility is not sufficient evidence of utility for the claimed compound (see *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). (2) Conservation and presence of a G-protein coupled receptor consensus sequence domain does not provide a specific, substantial and credible utility for the claimed compound because not all of the GPCR proteins of the family have the same utility. In other words, conservation of structure does not result in sufficient conservation of function to support having the same utility.

Further, there is no dispute in agreeing that HGPRBMY25 is a G-protein coupled receptor. It is also clear that the G protein-coupled receptor subfamilies show diverse modes of ligand binding and physiological functions. However, one skilled in the art would not know the specific and substantial utility or function of HGPRBMY25 protein, even if it was putative G protein coupled receptor because neither the prior art nor the specification provides for the asserted utility of the instant invention.

Although, HGPRBMY25 is capable of functionally coupling to Gq/1 G-proteins and associates this receptor with the direct regulation of the well-established phospholipase C (PLC) signaling pathway, it is not clear from the specification what PLC signaling pathways will be affected by the instant invention. Since, identify of the ligands that bind to HGPRBMY25 is not known, the modulation is also unknown. Neither the specification nor the prior art demonstrates a causal correlation or nexus of the claimed polypeptide with regulating the proliferation, survival, differentiation and/or activation of hematopoietic cell lineages contemplated by the instant specification. In addition, there is also functional relevance of the expression of HGPRBMY25 in lymph gland and the spleen. Since significant further research would be required by the skilled artisan to identify the role of HGPRBMY25 in the regulating the proliferation, survival, differentiation and/or activation of hematopoietic cell lineages, this asserted utility is not substantial

Since the instant specification does not disclose a "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claim Rejections - 35 USC § 112

9. Rejection of claims 22-37 under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention is maintained for those reasons given above in paragraph 8, with regard to the rejection of these claims under 35 U.S.C. §101.

10. The rejection of claims 22, 27 and 30 under 35 U.S.C. §112, first paragraph, as lacking in scope of enablement is withdrawn due to Applicants' amendments.

11. The rejection of claims 29 and 30 under 35 U.S.C. §112, first paragraph, as lacking in scope of enablement is withdrawn due to Applicants' amendments.

12. The rejection of claims 34-37 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention is withdrawn because Applicants have provided the relevant deposit information.

13. The rejection of claims 22-37 under 35 U.S.C. §112, second paragraph, as being indefinite is withdrawn due to Applicants' amendments.

14. The rejection of claims 22-37 under 35 U.S.C. §112, second paragraph, as being indefinite due to the recitation of "HGPRBMY25" is withdrawn due to Applicants' persuasive arguments.

15. No claims are allowable.

16. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JANET ANDRES
PRIMARY EXAMINER

JB 4/05